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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,547	10/26/2005	Harvey Kaplan	1658-8/AMK	1415
<div>7590      06/28/2007</div> <div>Adrian M Kaplan Dimock Stratton 20 Queen Street West Suite 3202 PO Box 102 Toronto Ontario M5H 3R3, CANADA</div> <div>EXAMINER AUDET, MAURY A</div> <div>ART UNIT      PAPER NUMBER</div> <div>1654</div> <div>MAIL DATE      DELIVERY MODE</div> <div>06/28/2007      PAPER</div>				

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,547	<b>Applicant(s)</b> KAPLAN ET AL.	
	<b>Examiner</b> Maury Audet	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/14/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>05/05</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The present application has been transferred from former Examiner Young to the present Examiner.

#### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-6, in the reply filed on 4/16/07, is acknowledged. The remaining claims have been cancelled.

#### ***Information Disclosure Statement***

The information disclosure statement filed 05/12/05 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; ***each non-patent literature publication*** or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. [Other than the application of those references relied upon by the International Authority over the same claims 1-6, and also cited in the IDS, 2 of these 3 references (abstracts) have been independently retrieved by the Examiner].

#### ***International Search Report***

The International Authority searched/examined the identical claims 1-6 as presently elected. The Authority found three (3) references as each rendering obvious ("Y") claims 1-6:

1. BORATYNSKI JANUSZ: "Dry reaction of proteins with carbohydrates at 120 degrees C yield neoglycoconjugates" BIOTECHNOLOGY TECHNIQUES, vol.12, no.9, Sept.1998 (1998-09), p.707-710, XP009022491 [NOTE: Could not be found on Medline Search];

Art Unit: 1654

2. BORATYNSKI JANUSZ ET AL: "High temperature conjugation of proteins with carbohydrates" GLYCOCONJUGATE JOURNAL, vol. 15, no. 2, Feb. 1998 (1998-02), p. 131-138, XP009022617 (abstract); and

3. TARELLI EDWARD ET AL. "Lysine vasopressin undergoes rapid glycation in the presence of reducing sugars" JOURNAL OF PHARMACEUTICAL & BIOMEDICAL ANALYSIS, vol.12, no.11, 1994, p.1355-1361, XP009022490 (abstract).

The latter two references are applied against the same claims 1-6 below.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over TARELLI ET AL. (JOURNAL OF PHARMACEUTICAL & BIOMEDICAL ANALYSIS, vol.12, no.11,

Art Unit: 1654

1994, p.1355-1361, XP009022490). In view of BORATYNSKI II. (GLYCOCONJUGATE JOURNAL, vol. 15, no. 2, Feb. 1998 (1998-02), p. 131-138, XP009022617); and

TARELLI ET AL. teach that “lysine vasopressin undergoes rapid glycation in the presence of reducing sugars”. The primary teachings of Tarelli et al. are that “*lysine vasopressin (LVP) readily reacts with reducing saccharides both in lyophilized preparations and in aqueous solution. Incubation of LVP with, for example, lactose over a pH range of 3.0-8.5 in phosphate buffer or simply in water [ ] analyzed by reversed-phase HPLC [ ] and by FAB mass-spectral analysis of derivatives isolated after reduction with cyanoborohydride. [ ]*” (entire document, abstract). Tarelli et al. does not expressly teach a heating step following the lyophilization step in the protein glycosylation process therein.

BORATYNSKI II. teach “high temperature conjugation of proteins with carbohydrates”, namely “a new procedure was used to conjugate lactose and dextran with BSA without using coupling or activating reagents. The method is *simple, rapid and cheap*. Reducing sugars covalently bind to proteins when *lyophilized together and briefly heated to a high temperature*” (entire document, abstract). [Note: The extremely broad limitations as to temperature, hours of heating, number of sugar units (claims 3-6) are deemed inherent in Boratynski II, absent evidence to the contrary.]

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to heat the lyophilized protein in the glycosylation process of Tarelli et al. because Boratynski II. advantageously teach a protein glycosylation process whereby the lyophilized solution is heated thereafter, while Tarelli et al. teach all the other steps of the process including the use of a reducing agent such as cyanoborohydride. One of ordinary skill in

Art Unit: 1654

the art in protein glycosylation would have been motivated to apply the heating step of Boratynski II to the Tarelli et al. glycosylation process, based on the advantages of shown by the former in a protein glycosylation process found to be simple, rapid and cheap – essential concerns for any lab/skilled artisan managing said lab.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Claim Rejections - 35 USC § 112 2nd***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, step 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase “combining a quantity of one of a reducing sugar and a reducing polysaccharide” is unclear. Are these one in the same (e.g. a multi-functional compound)? Is one of each of the two different compounds respectively to be administered? Or one or the other? Both are sugars, the latter simply a larger sugar, so it is unclear what type so sugars/saccharides/polysaccharides is to be combined to carry out the glycosylation/glycating step and how much of the smaller or larger sugar or both? Amendment to distinctly claim the

Art Unit: 1654

invention or clarification is required, as the specification did not adequately describe the above to remove the indefiniteness thereto.

### ***Claim Observation***

In claim 1, line 3, for clarity, it is suggested that a --,-- be inserted after the 1<sup>st</sup> recitation of the term "solution" to separate/form a break between the two aspects of this step (1<sup>st</sup> combining/2<sup>nd</sup> lyophilizing).

In claim 2, line 2, for clarity and more consistency with Markush-style groupings, it is suggested that after the term "with" the claim replace the phrase to recite --an agent selected from the group consisting of sodium borohydride, sodium cyanoborohydride, or alkyl amino borane--.

### ***Conclusion***

No claims are allowed.

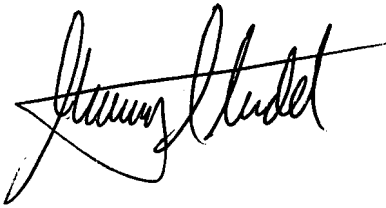
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1654

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 6/23/2007

A handwritten signature in black ink, appearing to read 'Maury Audet', with a large, sweeping flourish extending from the bottom left.

MAURY AUDET  
PATENT EXAMINER